

USSN: 09/390,846
Attorney Docket: I-1995.150 US D1
Amendment of November 1, 2006

REMARKS

In the Office Action of June 5, 2006, the Examiner objected to amended claim 13 for being drawn to an invention that is independent or distinct from the originally claimed invention as it recites different process steps and different parameters from those set forth in original claim 13.

For the purpose of furthering the prosecution of the present application, applicants have presently cancelled claim 13. However, applicants respectfully traverse the Examiner's conclusion as the prior amendment to Claim 13 merely introduced the specific process steps for preparing the vaccine. There were no different process steps indicated, the Amendment simply introduced the specific steps that made up the "formulating" single step in the claim as first written.

The Examiner rejected claims 1, 2 and 19 under 35 U.S.C. 112, second paragraph, for being indefinite. The Examiner objected that the phrase "molecular weight of about 37kD" was vague and indefinite, as the means by which the molecular weight was determined is not included in the claims.

Applicants presently amend the claims to recite that the claimed protein has a molecular weight of about 37kD "measured by sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS PAGE)." This amendment is supported in the specification on page 25, line 3 and page 26, lines 6, 7 and 21-27.

Claims 1, 2, 11, 19 and 20 stand rejected under 35 U.S.C. 102(b) for anticipation by Shirley. The Examiner relies on Shirley for teaching lactate dehydrogenase enzyme from *E. acervulina* prepared in a NaCl solution. The Examiner concluded that the protein of Shirley appears to be

Page 4 of 8

USSN: 09/390,846
Attorney Docket: I-1995.150 US D1
Amendment of November 1, 2006

the same as the claimed protein and the formulation in NaCl meets the limitations of the claimed process and composition as NaCl may be a pharmaceutical carrier. The Examiner continues to view the recitation of "vaccine" as an intended use.

The rejection of claims 1, 2, 11, 19 and 20 for anticipation over Shirley is respectfully traversed. The present claims are directed to an isolated and purified immunogenic protein having a molecular weight of about 37kD measured by SDS PAGE comprising a specific amino acid sequence. Shirley identifies enzymatic variations in *Eimeria* species in chickens including, among other things, that five different types of lactate dehydrogenase have been identified in five species of coccidia (*Eimeria*). This reference does not teach any purified protein, it does not teach a 37kD protein measured by SDS PAGE, and no immunogenicity for any of the proteins isolated, though not purified, is taught. The fact that the presently claimed protein is purified, is found to provide a protective immunity, is identified by its molecular size, 37kD measured by SDS PAGE, and comprises a specific amino acid sequence distinguish the claimed protein from the blot isolated by starch gel electrophoresis in the reference.

Claims 1 and 2 stand rejected under 35 U.S.C. 102(b) for being anticipated by Kucera. The Examiner has concluded that Kucera teaches a lactate dehydrogenase enzyme from *Eimeria acervulina* and the isolation and purification of the enzyme (page 296, figure 3). The Examiner has asserted that the characteristics such as the immunoreactive determinants and amino acid sequence would be inherent in the enzyme of the prior art.

The rejection of claims 1 and 2 over Kucera et al. is respectfully traversed, particularly with the present amendments. Kucera teaches the starch gel electrophoresis of lactate dehydrogenase and glucose phosphate isomerase of poultry coccidia. Figure 3 illustrates a contact print enzymogram of lactate dehydrogenase from various species of coccidia. It may be noted that in this starch gel electrophoresis model not all lactate dehydrogenase enzymes are found to have the

USSN: 09/390,846

Attorney Docket: I-1995.150 US D1

Amendment of November 1, 2006

same molecular weight. Although arguably isolated, there are no isolated and purified proteins, none are shown to be immunogenic and none are indicated to have a molecular weight of about 37kD measured by SDS PAGE. Moreover, no sequence information is provided. Accordingly, it is not possible to read Kucera and find that the claimed isolated and purified immunogenic protein having an identified molecular weight and comprising a specific amino acid sequence is suggested, let alone anticipated, by this reference.

Claims 1 and 2 stand rejected under 35 U.S.C. 102(b) for being anticipated by Nakamura et al. Nakamura is said to teach the lactate dehydrogenase enzyme from *Eimeria acervulina* and the isolation and purification of the enzyme. The other characteristics such as immunoreactivity and specific sequences are alleged by the Examiner to be inherent.

Examiner's rejection over Nakamura et al. is respectfully traversed for the same reasons set forth with respect to the other references, above. Like the others Nakamura et al. use starch gel electrophoresis for isolating *Eimeria* enzymes. These gels resulted in the isolation of lactate dehydrogenase enzymes from *Eimeria*, but nothing more. None of the enzymes isolated on the gels were purified. No characteristics such as showing that a protein having a particular molecular weight and comprising a very specific amino acid sequence, which provides a protective immunity in fowl, are taught.

None of the references cited disclosed purified immunogenic proteins having molecular weight of about 37kD measured by SDS PAGE and comprising the specific amino acid sequence shown in SEQ ID NO: 2. Moreover, none of the isolated, but not purified, proteins were even suggested to be effective in providing protection against coccidiosis. Applicants claim, with the present amendments, a vaccine effective for protecting poultry against coccidiosis comprising an isolated and purified immunogenic protein having a molecular weight of about 37kD measured by SDS PAGE and comprising the amino acid sequence shown in SEQ ID NO: 2. This is neither

USSN: 09/390,846
Attorney Docket: I-1995.150 US D1
Amendment of November 1, 2006

anticipated, suggested, nor obvious in view of the references cited.

The claims as presently amended do not recite a vaccine as an intended use, they recite a vaccine comprising an immunologically protective amount of a protein defined as being effective for protecting poultry against coccidiosis and having the specific characteristics recited above. No enzyme, not having the defining characteristics, in a NaCl solution could anticipate the present vaccine.

The Examiner has commented that upon further review of the application file, it was noted that applicants have not perfected the priority documents and, therefore, the priority date. Although the Examiner acknowledged that applicants were previously informed that such documents were found in application 08/676,882, the Examiner now states that that information was incorrect and that 08/676,882 is not the parent of this application and that there is no relationship (parent, divisional, continuation) between these applications.

Applicants respectfully question the Examiner's conclusion. In the original filing of this application, it is identified as being a divisional application of 08/676,882, and accordingly priority should be perfected. Applicants request the basis for the Examiner's conclusion that 08/676,882 is not the parent of the present application.

In view of the above, and with the present amendments, it is respectfully submitted that claims 1, 2, 11 and 20, all claims in this application, are in condition for allowance. Favorable action is solicited.

Should the Examiner consider that a conference would be helpful in advancing the prosecution of this application, she is invited to telephone applicants' attorney at the number below.

USPN: 09/390,846
Agency Docket I-1995.150 US DA
Amendment of November 1, 2006

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If necessary, the Commissioner is hereby authorized in this concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2334 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17.

Respectfully submitted,



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